The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JENNIFER L. HILLMAN

Application No. 09/781,117

ORDER UNDER 37 CFR § 41.50(d)

MAILED

AUG 3 1 2005

U.S. PATENT AND TRADEMARK OFFICE Board of Patent Appeals and interferences

Before WILLIAM F. SMITH, ADAMS and GRIMES, <u>Administrative Patent Judges</u>.

ADAMS, Administrative Patent Judge.

ORDER UNDER 37 CFR § 41.50(d)

Under the provisions of 37 CFR § 41.50(d), we require appellant to address the following matters:

<u>First</u>, we invite attention to commonly assigned Application No. 09/078,402 ['402] where, according to Patent and Trademark Office (PTO) records, the applicants filed a Notice of Appeal from the examiner's final rejection on October 4, 2001.² After a briefing stage, the Board entered a decision into the record of the '402 application,

¹ "The Board may order appellant to additionally brief any matter that the Board considers to be of assistance in reaching a reasoned decision on the pending appeal. Appellant will be given a non-extendable time period within which to respond to such an order." 37 CFR § 41.50(d).

² The named inventors in Application No. 09/078,402 are Jennifer Hillman, Neil C. Corley, Karl J. Guegler, Chandra Patterson and Mariah Baughn. The applications are commonly assigned.

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affirming the examiner's final rejection of claims 3, 6, 7, 9-12, and 19-24 (Appeal No. 2003-1115, BPAI 2004).

We think it clear that Appeal No. 2003-1115, in Application No. 09/078,402, bears close relationship to the instant appeal. In Appeal No. 2003-1115, the claims were drawn, inter alia, to an isolated polynucleotide encoding a polypeptide comprising an amino acid sequence selected from the group consisting of: SEQ ID NO:3; residues 31 through 40 of SEQ ID NO:3; and SEQ ID NO:5 (claims 3, 6, 7, 9, 10, and 21), host cells and methods of making the encoded proteins (claims 11 and 12). Included among the issues presented for appeal was whether the applicants' claims were supported by a disclosure of utility sufficient to satisfy 35 U.S.C. § 101.

In Appeal No. 2003-1115, appellants asserted that "the claimed invention ha[d] numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of diseases..., none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions." Decision, page 12. In addition, appellants argued that the claimed polynucleotides are useful in, among other things, "gene and protein expression monitoring applications." Id. Appellants relied on the declaration of Dr. Tod Bedilion to support their argument that the claimed polynucleotides have patentable utility because they can be used to monitor gene expression. See e.g., Decision, pages 12-15. Further, appellants asserted that the claimed polynucleotides encode proteins that "are in the class of 'apoptosis-associated proteins." Decision, page 19. In this regard, appellants asserted "[i]n order to demonstrate utility by membership in a class, the law requires only that the class not contain a substantial number of useless members.... That is true regardless of how the

claimed invention ultimately is used and whether or not the members of the class possess one utility or many." Id.

The previous Merits Panel reviewed governing principles of law; the Bedilion Declaration; and addressed and rejected the applicants' arguments, concluding that "[a]ppellants' disclosure in th[at] case does not provide a specific benefit in currently available form, and therefore lacks the substantial utility required by 35 U.S.C. § 101." Decision, page 28. Accordingly, the rejection of all claims under 35 U.S.C. § 101 in Application No. 09/078,402, was affirmed.

Like the claims in Application No. 09/078,402, the claims in this appeal are drawn to an isolated cDNA and a composition comprising the cDNA (claims 1-3), a vector and host cells comprising a cDNA (claims 4 and 5), and a method of producing a polypeptide encoded by the cDNA (claim 6). All of the appealed claims stand rejected under 35 U.S.C. § 101 and § 112, first paragraph, because "the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility." Answer, page 3.

The Appeal Brief in this appeal includes essentially the same line of argument addressed by the previous Merits Panel in Appeal No. 2003-1115 (Brief, pages 13-33). For example, appellant argues "the claimed invention has numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease, none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions" (Brief, page 5). Appellant relies on the Bedilion Declaration to support her assertion that the claimed invention has use in gene expression monitoring

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applications.³ See e.g., Brief, pages 5-6 and 8-11. In addition, in support of her assertion (Brief, page 18), "the claimed polynucleotide encodes a polypeptide in the DDP/TIM family...", appellant asserts "[i]n order to demonstrate utility by membership in a class, the law requires only that the class not contain a substantial number of useless members.... That is true regardless of how the claimed invention ultimately is used and whether or not the members of the class possess one utility or many." Id.

On these facts, we require that appellant explain why we should address these arguments anew in this case. Since these same issues have been raised previously in Appeal No. 2003-1115, why would the previous Panel's treatment of these issues not be dispositive here? In particular, why should the facts and arguments set forth in appellant's Appeal Brief lead to a different conclusion than that reached by another Panel in Appeal No. 2003-1115 rejecting the same line of argument? We note in passing that the applicants did not request rehearing on the same record within two months from the date of the decision in Appeal No. 2003-1115. Rather, according to PTO records, the application was abandoned.

Second, appellant states that "[t]here is no dispute that the claimed invention is in fact a useful tool in cDNA microarrays used to perform gene expression analysis."

Brief, page 8. However, the assertion that "[t]here is no dispute that the claimed invention is in fact a useful tool" appears to be incorrect. See, e.g., Answer, page 7,

³ We note, however, that the examiner did not consider the Bedilion Declaration on this record because it was not timely filed. <u>See</u> Answer, page 7.

wherein the examiner states:

[a]ppellant states that "the claimed polynucleotides can be used as highly specific probes in, for example, cDNA microarrays", and that "[g]iven the fact that the claimed polynucleotides are known to be expressed, their utility as a measuring and analyzing instrument for expression levels is as indisputable as a scale's utility for measuring weight." This argument has been fully considered but is not deemed persuasive.

Accordingly, on this record, it appears that there <u>is</u> a dispute whether the claimed invention is a useful tool in cDNA microarrays.

Explanation or clarification of this apparent discrepancy is required.

Third, based on our review of the file wrapper, we do not find any indication in the record that appellant has submitted into the record:

- the April 9, 2000, article published by the Bloomberg News Service (Appeal Brief, page 14);
- the February 10, 2000, article in the Wall Street Journal (id.); or
- evidence reflecting the work by C.V. Therapeutics (<u>id.</u>).⁴

Accordingly, explanation or clarification is required respecting just what evidence is of record which would support appellant's argument in the Appeal Brief, page 14.

Conclusion

In conclusion, we require appellant to address the foregoing matters "deemed appropriate for a reasoned decision on the pending appeal." 37 CFR § 41.50(d)(2003).

⁴ Generally speaking, the submission of evidence after a case has been appealed would be considered untimely. As stated in 37 CFR § 1.195 (rev. 2, May 2004), "[a]ffidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented."

We caution, however, that this is not an invitation to expand on points raised in the Appeal Brief or to rehash arguments already set forth in the Appeal Brief. This is not an invitation to raise arguments or issues on appeal, or to collaterally attack the decision in Appeal No. 2003-1115. See 37 CFR § 41.37(c)(1)(vii) ("Any arguments or authorities not included in the brief or a reply brief filed pursuant to § 41.41 will be refused consideration by the Board, unless good cause is shown"). Appellant's response should be confined to the matters outlined above.

Time Period For Response

A period of one month from the date of this order is set for appellant's response.

This time is non-extendable.

Failure to respond in a timely manner will result in <u>dismissal of the appeal</u>.

37 CFR § 41.50(d)

William F. Smith

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

BOARD OF PATENT

APPEALS AND

INTERFERENCES

Eric Grimes

Administrative Patent Judge

Appeal No. 2005-2384 Application No. 09/781,117

INCYTE CORPORATION EXPERIMENTAL STATION ROUTE 141 & HENRY CLAY ROAD BLDG. E336 WILMINGTON DE 19880